

## **REMARKS**

### **I. THE STATUS OF THE CLAIMS**

Claims 1, 3, 5, 6, 8-17, 19 and 23-27 are pending in the application. Claims 1-6, 8-17, 19, 21 and 23-27 are rejected.

### **II. THE OBJECTION TO THE CLAIMS**

The final Office Action objects to the claims, asserting that the two claims identified as claim 26 should be renumbered as claims 26 and 27. In response, Applicants have renumbered the claims accordingly. Reconsideration and withdrawal of the objection to the claims are respectfully requested.

### **III. THE REJECTIONS UNDER 35 U.S.C. § 103**

The final Office Action maintains the rejection of claims 1-6, 8-17, 19, 21-25 under 35 U.S.C. § 103 as being obvious over Gowan (U.S. Patent No. 5,374,659), Gergely et al. (U.S. Patent No. 5,834,019), Patel et al. (U.S. Patent No. 6,569,463), Eichman (U.S. Patent No. 5,980,882), McNamara et al. (U.S. Patent No. 6,423,298), Hagemann et al. (U.S. Patent No. 5,211,957) and Saeedi et al. (Prevention of Crystal Growth in Acetaminophen Suspensions by the Use of Polyvinyl Pyrrolidone Bovine Serum Albumin; DARU, Volume 11, Number 3 (2003)). In particular, the final Office Action asserts:

Applicant argues, neither Gowan, Gergely et al., Patel et al., Eichman, nor Hagemann et al. disclose the use of from above about 0 to about 5% weight per volume polyvinylpyrrolidone as a nucleation inhibitor and the use of from about 0.005 to about 0.1% weight per volume of an amino polycarboxylic acid compound to import improved pH and viscosity stability in a pharmaceutical composition. Examiner states the references in fact do teach such ranges. See modified rejection above.

See final Office Action at page 10. The final Office Action then asserts that Patel et al. discloses the use of 5 % weight per volume polyvinylpyrrolidone and Eichman discloses the use of 0.1 to 50 percent by weight, preferably about 1 percent by weight EDTA. See final Office Action at page 5. Applicants respectfully traverse the rejection.

Patel et al. discloses a solid pharmaceutical dosage form that includes a solid carrier comprising a substrate and an encapsulation coat on the substrate. See Abstract. Example 6 of Patel et al. discloses the preparation of a seal coating comprising 5 % polyvinylpyrrolidone. See col. 46, lines 15-32.

Eichman discloses a pharmaceutical composition comprising a drug-resin complex and a chelating agent in which the composition is in the form of a solid or a gel. See Abstract. Eichman discloses:

The content of EDTA in the drug-resin complex in the final dosage form may vary from about 0.001% to 10% by weight, but is preferably about 0.1 to 0.75% by weight for solid dosage forms and 0.005 to 0.2% by weight for suspensions. The mixture of drug-resin complex, chelating agent, and solvating agent may be dried to remove all but tightly bound water, or used without drying.

See col. 12, lines 54-59.

Applicants submit the references cited do not disclose the use of a pharmaceutical composition having the ingredients as claimed.

The final Office Action maintains the rejection of claims 1-6, 8-17, 19 and 21-25 under 35 U.S.C. § 103 as being obvious over Reinhardt et al. (U.S. Patent No. 6,217,998) in view of Hansenne et al. (U.S. Patent No. 6,916,464), Walch (U.S. Patent No. 6,790,847) and Patel et al. (U.S. Patent No. 6,569,463). Applicants respectfully traverse the rejection.

Reinhardt et al. discloses a liquid makeup composition that comprises 3.0 % polyvinylpyrrolidone and 0.05 % EDTA. See Example XV at col. 10, lines 40-59.

Hansenne et al. discloses a sunscreen composition that preferably has a pH which is compatible with the skin, preferably from 3 to 9 and more preferred from 3.5 to 7.5.

Walch discloses a drug composition that contains loratadine. See Abstract. Walch discloses that the composition may also contain one or more cosmetic excipients. See col. 5, lines 5-8.

Patel et al. is discussed above.

Applicants submit the references cited do not disclose the use of a pharmaceutical composition having the ingredients as claimed.

Reconsideration and withdrawal of the rejection of claims 1-6, 8-17 and 19, 21-25 under 35 U.S.C. § 103 over Reinhardt et al. in view of Hansenne et al., Walch and Patel et al. are respectfully requested.

#### **IV. Conclusion**

Early consideration and prompt allowance of the claims are respectfully requested. If there are any fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 10-0750/MCP5017US/LAD.

Respectfully submitted,

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